

REMARKS

The amendments set out above and the following remarks are believed responsive to the points raised by the Office Action dated August 5, 2002, and discussed during the interview with Examiners Menon and Walker on November 6, 2002. It is also believed the amendments and remarks are responsive to the points raised by Examiner Menon (as per Examiner Walker's instructions) during subsequent (after the interview) telephonic discussions on November 6 and 12. In view of the amendments set out above and the following remarks, reconsideration is respectfully requested.

As an initial point, Applicants' representatives (the undersigned and Leah Oubre Robinson) greatly appreciate the courtesy shown them by Examiners Menon and Walker, and further appreciate their careful consideration of the arguments presented during the interview.

The Present Invention

The present invention relates to filter devices, systems, and methods for processing biological fluid. Claims 1, 2, 4-7, 9-14, and 17-25 are pending.

The Pending Claims

Claims 3 and 8 have been canceled, and Claims 1, 2, 4-7, and 9-14, and 17-20 remain pending. Claims 21-25 are added by this amendment.

Claims 1, 10-14, and 19 have been amended, and claims 21-25 have been added, to describe the invention more clearly. No new matter has been added, the basis for the amended claim language may be found within the original specification, claims and drawings.

Claim 1, 10, 14, and 21 are supported at, for example, page 6, lines 14-16. Claims 22, 24, and 25 are supported at, for example, page 6, lines 16-17. Claim 23 is supported at, for example, page 6, line 36, through page 7, line 1. Entry of the above is respectfully requested.

Separate pages setting forth the precise changes to the claims, as well as the text of all the pending claims (amended and non-amended), are enclosed herewith.

At the interview, Applicants' attorneys discussed the nature of the present invention and the disclosures of the cited references. The claims have been amended in the manner discussed at the interview, so as to more particularly set out Applicants' invention.

During the interview, Applicants submitted that since none of the cited references, i.e., U.S. Patent Nos. 5,783,094 to Kraus and 5,406,581 to Onodera, teach or suggest the claimed embodiments, there is nothing in the cited references that would lead one of ordinary skill to the claimed invention.

The Office Action

For convenience, the following remarks will address the various comments and rejections in the same order they were raised in the Office Action, and the subsequent telephonic discussions with Examiner Menon.

The Office Action indicated the application did not contain an abstract of the disclosure as required by 37 CFR §1.72(b). As provided herewith, the abstract as published in the International publication is submitted.

Claim 13 was rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. According to the Office Action, the claim included a term that lacked proper antecedent basis.

It is believed Claim 10 provided the proper antecedent basis, however, it is believed the amendment to Claim 13 renders the rejection moot. Thus, it is respectfully submitted that the basis for rejection under 35 USC §112 has now been overcome and should be withdrawn.

Claims 3 and 20 were rejected under 37 CFR §1.75 as being substantially duplicative of claim 2, and claim 18 was rejected under 37 CFR §1.75 as being substantially duplicative of claim 17.

Claims 2 and 20, as well as 17 and 18, differ in scope, and thus, it is submitted the rejection is improper. Claim 3 has been cancelled, thus rendering the rejection of that claim moot.

Claim 10 was rejected under 35 USC §102 as anticipated by U.S. Patent No. 5,783,094 to Kraus et al. (hereinafter referred to as "Kraus").

Claims 1-9, 11-14, and 17-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kraus in view of U.S. Patent No. 5,406,581 to Onodera et al. (hereinafter referred to as "Onodera").

Each of these rejections is respectfully traversed.

As discussed during the interview, Kraus teaches a filter allowing red blood cells to pass therethrough (e.g., col. 4, lines 32-35), and thus, neither discloses nor suggests the claimed embodiments. The fact that Onodera may teach a membrane for separating whole blood into a blood cell product and plasma (e.g., col. 4, lines 24-48) is of no import. Onodera simply does not cure the deficiencies of Kraus, and therefore, the combination also fails to render the present invention obvious.

New Rejection under 35 USC §102

During the interview, Examiner Menon agreed the proposed claims were patentably distinct over the disclosure of Kraus. It is the undersigned's understanding, in view of Examiner Walker's comments, and the subsequent discussions with Examiner Menon, that the proposed claims are considered to be patentably distinct over Kraus in view of Onodera, but all of the

claims, proposed and previously pending, are now rejected under 35 USC §102 as anticipated by U.S. Patent No. 5,587,070 to Pall et al. (hereinafter referred to as "Pall '070").

Examiner Menon indicated Pall '070 did not need to be submitted via an Information Disclosure Statement (IDS) with a Form 1449. However, Applicants, in order to minimize confusion in the record, are submitting Pall '070 herewith. Moreover, since Pall '070 is a continuation of U.S. Patent No. 5,217,627 to Pall et al. (hereinafter referred to as "Pall '627"), Applicants are also submitting Pall '627 herewith.

In view of the chronology of events, it is believed there is no fee associated with this submission. However, if there is an associated fee, authorization is given to charge Deposit Account No. 12-1216.

Examiner Menon is respectfully requested to place his initials in the appropriate area of the Form 1449, thereby indicating his consideration of the documents, and return the initialed Form to Applicants.

Response to the New Rejection

The new rejection is respectfully traversed.

It is alleged that Pall '070 discloses the claimed embodiment of the invention, and the following sections of Pall '070 were specifically brought to the undersigned's attention: col. 6, lines 35-50; col. 7, lines 1-5 and 13-20; col. 11, lines 13-15; col. 12, lines 13-18 and 30-35; col. 16, line 35 through col. 17, line 7; col. 18, lines 32-53; and col. 19, lines 61-63.

However, the claimed embodiments are not disclosed in Pall '070 (or in Pall '627), either in the referenced sections, or anywhere else in this document. While Pall '070 refers to a fibrous red cell barrier medium, a fibrous leukocyte depletion medium, and a membrane, there is no disclosure of the claimed embodiments of filter devices, or of the claimed embodiments of methods for treating a biological fluid.

For example, there is no disclosure in Pall '070 of a filter device for processing a biological fluid comprising a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet; a filter disposed in the housing across the fluid flow path, the filter comprising: a first filter element comprising a porous fibrous leukocyte depletion medium having a CWST of at least about 70 dynes/cm; and a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, said second filter element being disposed downstream of the first filter element; wherein the filter is arranged to allow plasma to pass therethrough and substantially prevent the passage of leukocytes and red blood cells therethrough.

There is also no disclosure in Pall '070 of a filter device for processing a biological fluid comprising a housing having an inlet and an outlet and defining a fluid flow path between the inlet and the outlet; a filter disposed in the housing across the fluid flow path, the filter comprising: a first filter element comprising a porous fibrous red cell barrier and leukocyte

depletion medium having a CWST of at least about 70 dynes/cm; and a second filter element comprising a porous membrane having a pore size of about 5 micrometers or less, said second filter element being disposed downstream of the first filter element; wherein the filter is arranged to allow plasma to pass therethrough and substantially prevent the passage of leukocytes therethrough.

It appears the rejection under Section 102 is based upon the references to various media in Pall '070. However, a proper rejection under Section 102 requires that a document disclose every element of the claimed invention. See, for example, *In re Bond*, 15 USPQ 1566 (Fed. Cir. 1990).

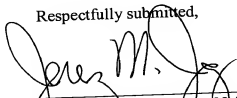
The rejection is improper, as Pall '070 does not teach a filter device comprising a housing and a filter across the flow path between the inlet and the outlet wherein the filter comprises first and second filter elements according to the present claims. Rather, Pall '070 teaches a plurality of devices with different filters, e.g., at col. 18, lines 43-50: "In the embodiment of the invention which includes a separation assembly 14, preferably a non-centrifugal separation device, the supernatant layer (e.g., PRP) may be passed through a leukocyte depletion assembly, and then passed through the non-centrifugal separation device 14, where it may be processed and separated into components. . ."

Accordingly, reconsideration of this rejection is respectfully requested.

It is believed this response summarizes all the issues discussed during the interview and during subsequent discussions. Should there remain any issues outstanding, the Examiner is invited to call the undersigned at his Washington, D.C. office.

In view of the amendment and remarks recited herein, the application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,



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